EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 1 OF 200:	
	2:12-MD-02327
Barbara A. Hill Case No. 2:12-cv-00806	MDL No. 2327
Constance Daino Case No. 2:12-cv-01145	Joseph R. Goodwin
Monica Freitas Case No. 2:12-cv-01146	U.S. District Judge
Patricia Ruiz Case No. 2:12-cv-01021	
Pamela Gray Wheeler Case No. 2:12-cv-00455	
Rebekah Bartlett (Pratt) Case No. 2:12-cv-01273	
Dawna Hankins Case No. 2:12-cv-00369	
Patricia Tyler Case No. 2:12-cv-00469	

DEPOSITION OF DOUGLAS GRIER, M.D.

March 22, 2016

Seattle, Washington

A Yes.
Q And the TVT Exact uses only laser cut mesh; is that correct?
A I don't know that to be true. I don't know whether or not they offer both mechanical or laser.
Q Okay. You just don't know, as you sit here?
A I don't know.
Q And the TVT Abbrevo is the new version of TVT-O; is that fair?
A Yes.
MR. KOOPMANN: I object just to this line of questioning as it relates to other products, for the record. This is supposed to be the TVT, TVT-O, and TVT-Secur, so --
Q (By Mr. DeGreeff) Okay. TVT Abbrevo uses only laser cut mesh; correct?
A I think that's correct.
Q Doctor, do you have an understanding of why mechanically cut mesh isn't used in those products?
A Well, I think the reason that there was a change in the product to laser from mechanical was to smooth out the edges so that it may be a little less irritating and perhaps have less of an inflammatory response of the tissues.
But clinically there's no difference between the

two. I've never noticed any difference in the placement or in the results of whether the sling was mechanical or laser cut. And --

Q And, Doctor, do you -- is that something you track within your office?

A I track all my patients in the office.

Q Do you track whether you're putting in laser cut or mechanical cut mesh?

A Well, if I'm putting in a TVT Abbrevo, then I assume that it's laser cut.

Q Okay. What if you're putting in one of the other products?

A I don't track it because I don't find it clinically relevant.

Q Okay. So it's not something you track within your office whether you're putting in mechanically or laser cut mesh?

A I don't actively track it because it's not -- it's -- I have no concern of one mesh cut or the other because I consider them equivalent. My experience with them is equivalent. But I do know that if I'm putting in a TVT Exact or an Abbrevo, that it's laser cut.

Q Okay. I guess my question's pretty simple. Do you or do you not track whether you're putting in a laser cut or mechanical cut mesh?

MR. KOOPMANN: Object to form. Asked

and answered.

THE WITNESS: I don't track it.

Q (By Mr. DeGreeff) And I think you mentioned that the reason for the switch from laser cut to mechanical was because the mechanical cut mesh can cause more irritation, given it's not as smooth on the edges?

A That's the theoretical consideration, yes.

Q And, Doctor, given that you don't track whether you're putting in laser or mechanical cut mesh, as you sit here, you can't say whether there's -- whether you're having an equivalent number of complications with one versus the other; correct?

A I know of no literature that shows any comparative difference between the two cuts, so I'm not aware that there is a problem for me to track. And in all my colleagues around the country, I know of no one who's tracking the results between mechanical and laser cut because there's no clinical significance because no one has identified there to be a problem.

MR. DEGREEFF: Can you read back my question?

(Question on Page 32, Line 8 read by the reporter.)

THE WITNESS: Yes.

Q (By Mr. DeGreeff) Is there -- is laser cut stiffer than

Any documents in there specifically that you remember reading front to back?
A. At this -- well, the IFU is in there, so I have read that in the past front to back. I read the historical documents about how TVT first was developed. And those are the ones that I remember in particular. There are a couple PowerPoint presentations that I probably was in -- present for or were delivered to me.
Q. Doctor, how many of these -- how many of these 34 documents do you think you actually reviewed in full?
MR. KOOPMANN: Object to form.
THE WITNESS: I can't give you an exact answer to that, but if you look through it, they're historical documents, so I don't -- I didn't spend much time at all with the Internet discussions between the Ethicon people and the corporation.
Q. (By Mr. DeGreeff) Did you -- in rendering your opinions, did you rely at all on internal company documents?
A. No.
Q. Why not?
A. I don't find them necessarily relevant.
Q. Why are they not relevant?
A. Well, because a lot of it has to do with research and development early on in the development of the products, and quite frankly, it's not -- I don't find it relevant

for me in rendering an opinion.

Q Did you review any of the design documents for the product?

MR. KOOPMANN: Objection. Form.

THE WITNESS: I don't recall design documents. You mean the original design of the -- of the mesh?

Q (By Mr. DeGreeff) Yeah, the design documents, the internal design documents for the mesh product?

A Well, if you could show me one, I could tell you whether I've reviewed it or not.

Q Well, do you know what I'm talking about when I say design documents?

A Not precisely, no.

Q Okay.

A Are you talking about before it was submitted to the FDA?

Q Well, have you reviewed the design device file?

MR. KOOPMANN: Objection. Form.

THE WITNESS: I don't recall.

Q (By Mr. DeGreeff) As you sit here, do you remember recalling any -- reviewing any internal Ethicon documents specifically relating to design of the TVT products?

A I'm sure I've looked at several, but none come to mind specifically.

Q Okay. If you think you looked at several, what did those

documents look like? What did they tell you?

A Oh, I don't recall. I looked at them prior to the Perry trial, I would imagine.

Q Okay. So -- and the Perry trial was about the TVT Abbrevo; correct?

A Correct.

Q And we're not here -- you're not rendering any opinions in this -- at this point generally about the TVT Abbrevo?

A No.

Q So my question is about design documents that would be relevant to the products that we're here about. Do you remember reviewing any of those design documents?

A Not specifically.

Q Well, not specifically. Do you remember reviewing any at all?

A If you put one in front of me, I can tell you whether I have or not.

Q Well, Doctor, you've got them -- are they on your reliance list?

A Some may be.

Q And did you review everything on your reliance list?

A I've -- in a general sense, yes. Specifically, I mean, there's a lot of documents, and some I may have just looked at the title and then what the conclusions were, and if something was interesting in there, I would go

A This binder contains multiple studies on TVT. It has my general report in it, and it has articles that I reviewed for my opinion. It has the different specialty body position papers on the use of mesh and different papers comparing Burches. It has an article on abdominal wall hernia repair using mesh.

Q And, Doctor, you don't have to go through every one of them in general. I'm just kind of trying to figure out in general what categories of documents are in there.

A Well, scientific papers. Papers that are produced by the different specialty bodies, like AUGS and SUFU, and multiple articles and abstracts. There's an article on the elongation characteristics of TVT Prolene. There's an expert report on mechanical mesh versus laser cut. There's an IFU for TVT-Secur.

There is a research and development memorandum on mesh for TVT-O. There is some comment on FDA hearing in 2011, the FDA executive summary. A Cochrane review of midurethral slings. Long-term efficacy of TVT --

Q Maybe we can do this. Is this all articles and clinical studies? Is that essentially what's in there?

A Yes.

Q Okay. And that -- is this a binder that you prepared, yourself?

A No.

Q Who prepared that binder for you?
A The attorneys, after sending me these articles for review.
Q Are those all articles that the attorneys sent you?
A Yes.
Q Okay. Those weren't articles that you did a systematic review and found them yourself?
MR. KOOPMANN: Objection. Form.
THE WITNESS: Well, I'm looking at one that I wrote, that I was -- I participated in. There are just multiple studies.
Q (By Mr. DeGreeff) That wasn't my question.
A Oh, sorry.
Q Did you do an independent systematic review and decide on which articles you wanted to review in rendering your opinions?
A Not this extensive. I've read the literature for the last ten, fifteen years, and so I keep abreast of it. So not every article is in journals that I have -- that I get.
Q Okay. So I think the answer to my question is no, you didn't do an independent systematic review for the literature that's on your reliance list?
A Yes, that's correct.
Q And you didn't put together that binder. Defense counsel

did.

A Correct.

Q And defense counsel selected the articles that are in that binder?

MR. KOOPMANN: Objection. Form. Misstates the record.

MR. DEGREEFF: I don't think it does.

THE WITNESS: Well, I don't know what they -- how they selected them.

Q (By Mr. DeGreeff) You --

A They're not all positive articles.

Q Well, that's true too, but you didn't select all of those; correct?

A Correct.

Q Those were selected for someone else -- by someone else for you?

A Yes.

Q And they were sent to you by defense counsel?

A Yes.

Q And did you review all of the articles in that binder?

A The majority of them, yes.

Q Okay. Did you review -- did you rely on all the articles in that binder?

A I relied on all those that I reviewed.

Q And which ones -- did you review those that were -- that

A My memory, last time I saw him was when I did a cadaver lab with about ten surgeons from around the country on the TVT-O. It was our first experience with the TVT-O, and we were using the device prior to having used it in our practices.

And another article by Leval and Waltigney on the one-year follow-up on TVT-O. And Leval's white paper on the TVT-O.

Q Who is Leval?

A Jean Leval is a Belgian urologist out of Liege, Belgium, as I recall, and he was the developer of the inside-out approach for transobturator slings.

Q Do you know Dr. Leval?

A I met him once. He does not speak English. Talked to him through a -- an interpreter.

Q You met -- did you meet Dr. Leval and Dr. Weisberg at Ethicon events?

A Yes. Yes.

Q So fair to say that that binder you're looking at contains just a bunch of materials that are on TVT-O?

A Yes.

Q And did you put that binder together, yourself?

A No.

Q Was that put together for you by defense counsel?

A Yes.

Q Did defense counsel select the documents that went into that binder?
A Yes.
Q Have you reviewed all of the documents in that binder?
A Well, I've reviewed them -- a lot of them I've reviewed before they ever were put in the binder, before I was ever asked to review them.
Q Okay. So my question was a little different than that.
Have you reviewed -- and I don't care when you reviewed them. Have you reviewed all of the lit- -- all of the documents that are in that binder?
A Well, no. The ones I haven't reviewed were the pre-FDA design documents, which are very tedious, and I didn't find relevant.
Q So fair to say, you did not review the design documents that were relied on by Ethicon for approval by the FDA?
MR. KOOPMANN: Objection to form.
THE WITNESS: That's true.
Q (By Mr. DeGreeff) Anything else?
A Well, there's just a bunch of minutes and discussions by, I guess, engineers within the -- within the company on the product specifications and the launch of the product.
Q And did you review those?
A I did not.
Q Why not?

A Well, because I don't find it relevant.
Q And that's the -- those are memos done by the engineers who designed the product?
A Correct.
Q Why did you not find that relevant?
A Well, because it's tremendously tedious, and it's not clinically relevant. It was how they developed the product and -- the device, and it's kind of too technical for my interest.
Q And you didn't -- so you didn't review that in rendering your opinions?
A No.
Q Did you review any documents related to the -- kind of the -- what you referred to as the tedious portion of the design of the -- of the document and getting FDA approval?

MR. KOOPMANN: Objection. Form.

THE WITNESS: There may be a few that I reviewed.

Q (By Mr. DeGreeff) Which ones? Any as you sit here that you remember?
A My patients' list at home.
Q I was wondering how that got in there.
A Yeah, that just got -- it fell in.

The ones I reviewed were -- see, a lot of this is

just -- it's not even in English. It's the documents that are -- came out of Belgium that aren't even translated, so I certainly didn't read those.

The others were just kind of how the sheath was developed, not the actual sling, but the sheath that helps place it. So these -- and, you know, this TVT flow of process qualifications, I looked at it. It's a very technical engineering document on the product production. I'm not an engineer, so it's not relevant to me. There's just a lot of that. How to package it, what kind of box it should be in, things --

Q So you're not an engineering expert; correct?

MR. KOOPMANN: Objection. Form.

THE WITNESS: I'm not an engineering expert, but I am an expert on the use and placement and management of vaginal mesh because that's what I've done a lot of.

Q (By Mr. DeGreeff) That doesn't make you -- you are not --

A It does not make me an engineer.

Q You're not holding yourself out as an expert in the field of engineering, are you, Doctor?

A No, of course not.

Q And fair to say, you're not holding yourself out as an expert in the field of transvaginal mesh design?

MR. KOOPMANN: Objection. Form.

THE WITNESS: I will say no. I will say, though, that -- that all of us give feedback to the companies that we use mesh, as to what might be better about it.

Q (By Mr. DeGreeff) I think we agree. My question is pretty simple. Yes or no, are you holding yourself -- yes, no, or you can't answer. Are you holding yourself out as an expert on the design of transvaginal mesh products?

MR. KOOPMANN: Objection. Form. Asked and answered.

THE WITNESS: Do I answer?

MR. KOOPMANN: Go ahead, yeah.

THE WITNESS: So I am not a product engineer that has designed mesh products. However, I have used them, and I have opinions about what -- what is good or bad about a particular product, which I have expressed to multiple companies when asked. So -- but I am not an engineer.

Q (By Mr. DeGreeff) Let's try this again. Doctor, yes, no, or you cannot answer my question as it's phrased: Are you holding yourself out as an expert in the design of transvaginal mesh products?

MR. KOOPMANN: Same objection.

A Yes.
Q Did you submit it to the -- to the --
A FPRMS, yes.
Q -- FPRMS?
And so given that you had that role, you still don't remember what that number was?
A Oh, it was the number of all the surgeries that you've done. No, I have no idea what that number is.
Q All of the surgeries that you've done since when?
A Well, in a six-month -- in a six-month period, but that's all -- that's general urology, female urology, whatever -- whatever surgical cases I was doing.
Q You also treat males as part of your practice; correct?
A Correct.
Q What percentage of your practice deals with treating men?
A Roughly 50 percent.
Q Are you a member of AUGS?
A No.
Q Why not?
A Well, I'm a urologist, and so the urologic focus for female urology is SUFU, society of uro-gynecon- -- urology and gyne- -- and -- female urology. And I'm a member of the AUA, but I'm not a member of AUGS. I have gone to several AUGS meetings in the past. The last one was this last October.

Q And what does AUGS stand for?
A American Urogynecology Society. If you want me to give you kind of a history of urogynecology, I can.
Q No, that's okay.
You've got teaching positions listed on your -- on Exhibit 2, which is your CV, on the second page.
A Yes.
Q Let's kind of talk about those. The first one is Ethicon Endosurgical Institute; correct?
A Yes.
Q And that obviously is something that is through Ethicon, the defendant in this case; correct?
A Correct.
Q How long have you been teaching for Ethicon Endosurgical Institute?
A Well, I started in the '90s, and then probably the last course I gave, I don't know the year. 2013 perhaps.
Q So you were doing that for roughly 15, 16 years?
A Yes.
Q And who takes those courses?
A Urologists and gynecologists take those courses.
Q And were you paid for those courses -- to give those courses?
A Yes.
Q And Ethicon paid you for that?

A Yes.
Q And was that done under a contract with Ethicon?
A Yes.
Q Would that be --
A Annual contracts.
Q It would be a one-year rolling contract?
A Uh-huh.
Q And was that -- was that pursuant to what I've seen called as the consulting agreement?
A Yes.
Q And that's not a course that's taught for any college?
A No, no. But over the years, I have taught courses at medical schools, in medical schools, and have taught urologists who are academics how to do these procedures.
Q And there's no continuing education given for taking an Ethicon Endosurgical Institute course, is there?
A No. And the reason being is that they don't charge the participants to go to the courses, so that because they're -- because they're there without a tuition, they don't -- they're not allowed to grant CME. Because, to grant CME, it has to go through a national body that credentials.
Q The question was a little different than that, a little more simple than that.

There's no continuing education given for Ethicon

in studies on the inventor's device?
A Oh, again, I have no idea. How would I know that information? I've not heard it.
Q Do you think they should?
A Should prevent? No.
Q Do you know whether Ethicon has any policies in place that prohibit inventors from participating in studies on the inventor's device?
A I'm not aware.
Q Do you think they should?
A It's -- I don't have an opinion.
Q It doesn't matter to you?
A No.
Q Doctor, are you aware of how long it took the -- it took Ethicon to get the TVT-O product to market?
A I don't recall the timeline.
Q Doctor, what is Provencia?
A I don't know.
Q Do you know what a failure modes and effect analysis is?
A That sounds like an engineering design study to look at physical properties of different products/materials.
Q Have you ever been involved in one of those analyses?
A No.
Q What should be in a failure modes and effects analysis?
MR. KOOPMANN: Objection. Form.

THE WITNESS: Well, can you give me a product or material that you want to apply it to?

Q (By Mr. DeGreeff) Mesh. What should be in a failure mode designs effect analysis for mesh?

MR. KOOPMANN: Objection. Form.

THE WITNESS: Well, one would be what its tensile strength is, elongation overload. Those would be the main ones.

Q (By Mr. DeGreeff) Have you ever -- did you review the -- any of the FMEAs in this case?

A I've seen some, yes.

Q For transvaginal mesh?

A Uh-huh.

Q Which ones?

A Oh, I think Guenther is one. Moalli has some. But there's Dietz study from Australia that described the bench loading and elongation.

Q You're talking about articles and studies; correct?

A Yes. But I -- as far as the -- you mean as far as corporate documents in terms of what they did prior to the product being released?

Q Yes.

A I would glance over them and not -- and not read them.

Q All potential hazards should be in the failure modes effects analysis for TVT; correct?

MR. KOOPMANN: Objection. Form.

THE WITNESS: Again, I don't know what that means.

Q (By Mr. DeGreeff) You don't know what a design failure modes effect analysis is?

A Well, I know -- I know what the term is, but when you're saying -- there's a difference between in vivo and ex vivo. If you're talking about bench testing products that the stresses that are put on them are greater than the physiologic stress in the body, I don't think those are relevant.

I mean, it's fine to do the studies to get a sense of what the burst strength is of mesh, but it's never going to be seen after it's deployed.

Q And you don't find those studies relevant, or those relevant?

A Well, it has a relevance, but it doesn't have a high significance.

Q You don't find them significant?

A It has a significance. I can't -- I'm not going to give you a degree of significance.

Q You didn't rely on them in giving your opinions in this case; fair?

A Well, when I looked at them, I want to make sure that the stressors of these meshes, after they're deployed in the

there was a surgical misadventure and, say, the mesh was placed through the wall of the bladder, then I would have to go after all that area that was involved.

But there's no reason to chase all of it out of the body because it's -- it's biologically inert where it is and doesn't need to be done.

Q (By Mr. DeGreeff) Do you believe that the mesh used in TVT-R is biologically inert?

A I think the -- there's a local inflammatory effect initially, which induces fibrosis, some scarring, some collagen deposition, angiogenesis into the -- into the monofilament, and then it settles down over time.

Q So you believe that long-term the -- the transvaginal mesh used in the TVT products is biologically inert?

MR. KOOPMANN: Objection. Form.

THE WITNESS: I don't know your definition of inert, but I would use the word quiet. I have patients who are out 15 years from slings that I have done and I've examined them and they're asymptomatic and they have great results, and they're not concerned with the sling in their body. It's not bothering them.

Q (By Mr. DeGreeff) Doctor, what's the definition of inert?

A Well, inert is nonactive.

Q So your definition of inert is nonactive?

A Yeah. That there's nothing going on.
Q So you believe that long-term transvaginal mesh is nonactive within a woman's body?
A In the vast majority of cases, I would say yes.
Q So when you remove mesh, you sometimes make the decision to leave portions of the mesh in because you believe long-term it's nonactive within a woman's body?
A Well, the only reason to remove a portion of mesh is if they are symptomatic in that area. So if one area there's a trigger point and they have pain and they haven't responded to conservative measures, you can remove the sling in that location, but you could leave the contralateral side alone if it's not bothering them. In fact, if you leave the majority of the sling in place, there's a good chance they'll remain continent.
Q So, Doctor, you have done TVT-R removal surgeries, correct, whether it was removing all of it or part of it?
A Along with multiple other companies, yes.
Q And you've done TVT-O removal surgeries, I'm assuming?
A Just portions. Just, again, the exposed area.
Q But you've done explant surgeries based on complications caused by TVT-O; is that fair? Not caused -- strike that. I know you probably aren't going to like that word.

You've done remove- -- you've done explant surgeries

of TVT-Os due to complications; correct?

MR. KOOPMANN: Objection. Form.

THE WITNESS: I have removed sections of TVT-Os for exposure. I can't remember any for any other reason.

Q (By Mr. DeGreeff) And is that something you track?

A Oh, I -- well, I track all my patients. I see them -- I try to see them on an annual basis, and if they don't agree, I try to make it every other year.

Q So do you have something in your office where you track the reason for each removal and what product it is you're removing?

A Their medical records.

Q Is that a list you would keep in your office somewhere?

A It's one I could retrieve.

Q So you have a list currently kept in your office of the product you removed and with -- with the reason for removal?

A No, I don't have a list.

Q And how many TVT-O removal surgeries have you done?

A Well, partial TVT-O, I would say a half dozen maybe.

Q What about TVT-R?

A Same. About a half dozen.

Q What about TVT-S?

A Maybe three or four.

Q So in your entire time working with transvaginal mesh, between TVT, TVT-O, and TVT-S, you believe you've only done 15 to 16 removal surgeries?
A I'm sure I've removed 35, 40 other products that are either transobturator or retropubic slings.
Q So you've only done 50 total removal surgeries in your time working with transvaginal mesh?
A Do you -- are you including POP repair, like Prolift or elevate, Apogee, Perigee, the other products?
Q Well, I was asking specifically about TVT, but sure, we can talk about those too.
A I mean, I don't keep numbers of it, but I've removed each of those products in the past.
Q That was going to be my question. Where's the tracking data on TVT-Rs that were removed, on the number of explants you've done?
A What do you mean by "tracking data"?
Q Is that something you keep track of in your office?
A No, I don't keep track of the numbers.
Q How long have you been doing removal surgeries? When did you first start doing them?
A Well, again, when you use the word "removal," I'll take out a specific area that may be exposed, or if there's a specific trigger point area of pain, I'll remove that part.

Are those included in the six, six, and three?
A. Yes. But I mean, the -- it's -- these numbers are not -- are not exact, by any means. I don't keep a log of them.
Q. Okay. How many days a week do you operate, Doctor?
A. Well, I don't know what you mean by operations. I do operations on Wednesdays in the hospital. I do operations on Tuesdays in my surgery center. And I do procedures on Mondays, but they could be any day of the week. I could do them night, weekend. So it varies on a week-to-week basis.
Q. So you don't have certain designated surgery days or times?
A. I do. Wednesdays for surgeries at the hospital, and Tuesdays in my surgery center.
Q. Okay. And do you do them all day, or what's the --
A. Depends on how many. As little as two or as many as all day.
Q. Okay.
A. Into the night.
Q. And we already talked about the fact that 50 percent of your practice is with men; right?
A. Yes.
Q. What percentage of your practice is related to treatment of stress urinary incontinence and POP?
A. Before the mesh litigation, it was at least 50 percent of

my entire practice was. At that point I was probably seeing one-third males and two-thirds females. But because of the shrinking volume of women who seek care for these problems, I do less and less each year.

Q And what percentage of your practice is related to treating TVM complications?

A Oh, less than 1 percent.

Q What percentage of your practice is related to the surgical treatment of TVM complications?

A Oh, I'd say less than 1 percent at this point. I don't see them that often.

Q Doctor, do you do anything within your office to track what percentage of the women that you do implants in are lost to follow-up?

A No.

Q Do you know what the national average is?

A No.

Q Do you know what the national average is on complications related to following implant surgeries with TVM?

A Oh, there's several papers that provide those numbers.

Q Certainly greater than 1 percent, isn't it?

A I think it's about 3 and a half percent.

Q So you believe 3 and a half is the rate?

A One recent paper I reviewed, that was the rate of complications that required something to be done.

Q Ever seen any others that's different?
A Oh, it's all -- it depends on what study and what cohort. If you happen to be a referral center, you're going to see a lot more because a lot of gynecologists aren't comfortable with doing repairs or revisions.
Q And a lot of patients aren't comfortable going back to the person who put in an implant that gave them complications; fair?
A That's -- complications in general, for all of medicine, a lot of times patients have unrealistic expectations and will go elsewhere when they don't have exactly the outcome that they want. That's very common, not just in this.
Q Okay.
A It's common with all complications.
Q So it's typical for anybody -- any surgeon to have a significant loss to follow-up; is that fair?
A It really -- it depends on what community you're in. If there are -- if you're in a smaller community and there's less choices of where to go, a lot of times, if a patient has a complication and doesn't see you, they'll see one of your colleagues, and they'll -- we can discuss it, they'll -- you'll find out about it. There's many a time where I've called a physician to tell them that a patient of theirs came in and this was their concerns.

resolve in some patients, is a risk associated with TVT devices?

A It's associated with all pelvic surgery, whether a device is used or not.

Q Do you agree that it's associated with TVT devices?

A Directly, I can't prove that it's directly associated.

Q You agree that chronic pain in the groin, thigh, leg, pelvis and/or -- pelvic and/or abdominal area is a risk associated with TVT devices?

A Slings that go through muscle can cause some -- chronic pain. Rarely, but can cause chronic pain, and through -- you're talking about transobturator. There's some thigh pain associated regardless of what product is used. It's a very small number.

Q Do you agree with the statement that chronic --

A What I can't -- what I can't agree on is if it caused chronic pain, why wouldn't every case you do result in chronic pain? The few cases that patients have chronic pain after a pelvic surgery, I can't identify a specific cause of it.

Q Doctor, do you agree one or more revision surgeries is a risk associated with TVT devices?

A It's a risk, yes. A low risk, but it is a risk.

Q Agree that TVT removal may be needed, and that removal may require significant dissection?

A Depending on the cause, it's a possibility.

(Discussion off the record.)

EXAMINATION

BY MR. KOOPMANN:

Q Dr. Grier, you reviewed case-specific medical records in connection with forming your opinions on the cases in which you were asked to form case-specific opinions; correct?

A Yes, yes.

Q And you reviewed those records before you drafted those reports; correct?

A Yes.

Q The reliance list that Counsel was asking some questions about, did you come up with the title of that document?

A No.

Q Okay. Do you use the term "reliance list" in your practice?

A Not at all.

Q Is it your understanding that that's a list of materials that one of the law firms involved in this litigation has sent you over the years?

A Yes.

Q And in your reports regarding the TVT and TVT-O midurethral slings that we've marked as Exhibit 14, and you report regarding the TVT-Secur slings, did you cite a

number of articles and position statements and peer-reviewed literature and things like that?

A Yes, I did.

Q Okay. And are those the materials that you're primarily relying on in support of your opinions regarding --

A Yes.

Q -- these devices?

A Yes.

Q The FDA guidance document that some questions were asked about very early in the deposition, that's something that you considered in forming your opinions, but it isn't all you considered in judging the adequacy of the instructions for use for the TVT, TVT-O, and TVT-Securs; correct?

A That's correct.

Q You also considered your use of those products throughout the past?

A Yes.

Q And you considered the sort of results that you achieved in treating patients with those products; correct?

A Yes.

Q Did you also consider the complications that you saw develop in your practice from your use of those products?

A Yes.

Q And all of that went into forming your opinions regarding

the adequacy of the warnings in --

MR. DEGREEFF: Objection. Form.

Q (By Mr. Koopmann) -- in the IFUs for the TVT, TVT-O, and TVT-Secur?

A That's correct.

MR. DEGREEFF: Object to the form.

Q (By Mr. Koopmann) And did your analysis and your reading of the literature that you cited in your reports for the TVT, TVT-O, and the TVT-Secur, and the efficacy and complications discussed in that literature, also go into your analysis of the adequacy of the warnings in the IFUs for the devices we're here to talk about today?

MR. DEGREEFF: I'm going to object to form. Do you just want to give me a running objection on leading?

MR. KOOPMANN: Sure.

MR. DEGREEFF: Okay. Running objection on the fact that all of these questions are leading.

THE WITNESS: Yes. I considered all -- all that information in -- in determining what I think is appropriate for the IFU.

Q (By Mr. Koopmann) And the opinions that you set forth in the reports we've marked as Exhibit 14 and 15 regarding the TVT, TVT-O, and TVT-Secur slings, you hold those

opinions to a reasonable degree of medical certainty?
A Yes.
Q You don't hold yourself out to the community as a design expert; is that fair?
A That is fair.
Q But are you an expert in urologic surgery?
A Yes.
Q And are you an expert in the materials used in urologic surgery?
A Yes, I am.
Q And you don't hold yourself out to the community as a warnings expert; correct?
A No, I don't.
Q But you've used a lot of medical devices throughout your career?
A Yes.
Q Dozens, certainly?
A Yes.
Q Hundreds?
A Yes.
Q And before you use a medical device, you read the instructions for use accompanying the device?
A I do.
Q And after treating patients with devices, you get a sense of what sort of complications you see?

A Yes.
Q Okay. And you factored in all of that experience with the TVT, TVT-O, and TVT-Secur slings in forming your opinions about the warnings accompanying those devices?
A I have.
Q You've been provided -- you were asked some questions earlier about being provided articles, including some of the articles we've got in front of us here today. But did Ethicon provide -- or Ethicon's counsel provide all of these articles the first time that you saw them, or did you read them in the course of your reading as a surgeon?
A Oh, many of them I read in the course of my reading.
Q You were asked some questions about Professor Ulmsten and payments that he's received. Has Professor Ulmsten's data regarding the TVT sling been reproduced by many other studies?
A Yes, it has, all around the world. It's the most studied of all the pubovaginal slings, the urethral synthetic slings.
Q Do you practice evidence-based medicine?
A I do.
Q And what does that mean?
A That means what I choose to provide for my patients has scientific scrutiny and is as safe and efficacious as

what is the standard of care.

Q And are there different levels of evidence?

A There is different levels of evidence. From the bottom, which is anecdotal reporting, to the top, which is, say, Cochrane review, meta-analysis, systematic reviews.

Q Where do internal company emails fall on the hierarchy of levels of evidence?

A They don't fall at all, in any of it.

Q Where do failure modes and effects analyses fall in the hierarchy of levels of evidence?

A They don't fall at all in the levels of evidence.

Q The opinions that you've expressed in your reports regarding the safety and efficacy of the TVT, TVT-O, and TVT slings, are those opinions based in part on your education, including your medical school and residency?

A Yes.

Q Is it also based on continuing ed courses?

A Yes.

Q Are those opinions about the safety and efficacy of the devices based on your clinical training and experience?

A Yes.

Q Are those opinions about the safety and efficacy of the devices based on your review of the peer-reviewed literature, book chapters, podium, and poster presentations and abstracts?

A Yes.
Q Are they also, your opinions, based on professional society position statements?
A Yes.
Q Are they also based to some extent on ongoing discourse between yourself and your colleagues regarding these devices?
A That is true.
Q And your opinions are based in part on your review of complications discussed in the literature and those that you've seen in your practice?
A Yes.
Q Are the complications that you've seen in your practice consistent with the warnings that you see listed in the adverse reactions section of the IFUs for the TVT and TVT-O and TVT-Secur prior to 2015?
A Yes, they're consistent.
Q Is chronic pain a risk of any pelvic floor surgery?
A Yes, it is.
Q It is a risk of the Burch procedure?
A Yes, it is.
Q It is a risk of pubovaginal sling procedures?
A Yes, it is.
Q Is dyspareunia a risk of any pelvic floor surgery?
A Yes.

Q And are any complications that occur after any surgery -- do they have the potential to be temporary or chronic?
A Yes.
Q And do any complications that occur following any pelvic floor surgery have the potential to be mild, moderate, or severe?
A Yes.
Q Do you have an opinion as to whether chronic pain and dyspareunia are common complications with any pelvic floor procedures, that all pelvic floor surgeons are expected to know?
A Yes.
Q And what is that opinion?
A That opinion is very common, and every pelvic floor surgeon knows that it is a possible complication.
Q When you were teaching professional education courses for Ethicon, did any of your colleagues ever express any concern about the complications listed in the IFU?
A Well, yes, we discussed it. We would discuss it about -- just about every meeting.
Q Did they express any concerns about the complications they saw listed?
A No. They're known and expected.
Q How many TVT slings would you say you've implanted, if you could estimate?

A Probably 1,500.
Q How many TVT retropubics? Let me be more specific.
A At least 500.
Q And how many TVT-O slings have you implanted, if you could estimate?
A Another 500.
Q And how many TVT-Secur slings would you say you've implanted?
A Oh, probably between 50 and 75.
Q How do the complications that you've seen in your practice from the TVT, TVT-O, or TVT-Secur slings compare with the complications reported in the literature?
A They're very similar.
Q And how do the complications that you've seen -- strike that.

Is it basic medical and surgical knowledge that postsurgical pain can be chronic or temporary?
A Yes.
Q Is it basic surgical knowledge that, when an adverse reaction occurs, further surgery may be required to correct it?
A Yes.
Q And did you know, prior to ever putting in a TVT, TVT-O, or TVT-Secur sling in a patient, that tissue in-growth would occur in the pores of the sling?

A Yes.
Q And based on that understanding, did you also have an understanding that if, for some reason, part of that sling needed to be removed, that dissection would be required?
A Yes.
Q Did you have many patients who experienced no complications in connection with a TVT surgery?
A Yes.
Q And is the same true for TVT-O surgeries?
A Yes.
Q And is the same true for TVT-Secur surgeries?
A Yes.
Q When you did have a patient that received one of those slings who had a complication, did you treat those complications?
A Yes.

MR. DEGREEFF: I hope so.

Q (By Mr. Koopmann) And you were asked some questions earlier about follow-up of your patients in your practice; is that right?
A Yes.
Q From time to time, patients don't return to you; that's true?
A That is true.

Q Okay. And that's true of any doctor, presumably?
A It is true of all of us, yes.
Q When patients go to other doctors after they have a complication following one of your surgeries, do you often learn about the fact that they went to another doctor?
A Yes.
Q And how do you do that?
A They usually out of courtesy will call me, or if the reverse is true, I will call them.
Q Can you think of a single randomized control trial that says the TVT mesh degraded or was cytotoxic?
A No.
Q And does that apply to the TVT-O sling mesh and the TVT-Secur mesh?
A I know of no randomized control trials that show any degradation in any of the mesh products.
Q They all have the same mesh; right?
A For this line of -- for Ethicon, yes, they're all the same weave, same monofilament.
Q For those company documents that you were provided and read, did any of them change your opinions that you formed based upon the peer-reviewed literature that you've reviewed and your experience using the slings?
MR. DEGREEFF: I'm going to object to

the form. He said he didn't read any review.

THE WITNESS: No, I didn't -- none of them changed my opinions.

Q (By Mr. Koopmann) And while Ethicon's counsel may have sent you some articles in the course of your work in this litigation, did you also do your own searches for articles and literature?

A Yes.

Q You don't think chronic pain occurs with any of the TVT family of products due to any defect in the mesh; correct?

A That's correct.

Q You said that, with respect to -- I think it was stiffness, you said there was a point at which you would see diminishing returns if you had a very elastic sling.

What did you mean by that?

A Well, if --

MR. DEGREEFF: I'm going to object to form. I think that misstates.

THE WITNESS: Do I answer?

Q (By Mr. Koopmann) Yes.

A So if a mesh is too soft and has very, very little stiffness or integrity, it no longer supports the tissues that it's -- that it's designed to support.

Q Okay. Is it more lucrative for you to do surgery or to

give lectures for device companies?

A To do surgery and be in the office.

Q So why is it that you've devoted a significant amount of time to giving lectures for device manufacturers or pharmaceutical manufacturers?

A Because I enjoy teaching, and I like the collaboration with other physicians around the country, and I find it to be professionally enhancing.

Q In what way?

A Well, because I've developed a network of friends around the country, of colleagues that I can call if I have a problem with a particular patient. Some of the brighter minds that are in our profession. And it also -- it requires me to stay vigilant in terms of training and study.

Q Counsel asked a question about RCTs that have the primary end point of safety regarding the TVT.

My question for you is, do all or almost all of the RCTs that you have reviewed on the TVT and TVT-O and TVT-Secur products discuss complications?

A Yes. It may not be the primary outcome, but every one of them comments on percentages of complications, adverse outcomes, and issues about pain.

Q You were asked some questions about chronic pain associated with the TVT sling, and one of the articles

that you had out a few minutes ago was this Tommaselli systematic review and meta-analysis.

A Yes.

Q That's an article that you reviewed and relied on in forming your opinions?

A Yes.

Q And in that study, there were 3,974 retropubic TVT -- I'm sorry -- retropubic sling patients?

A Yes. And -- well, it was retropubic and transobturator, total.

Q Right. But if you look at Table 3 of that study -- Table 3.

A Got it.

Q There were 3,974 total retropubic patients in that study?

A Yes.

Q And then there were a total of 2,432 transobturator patients?

A That's correct.

Q And then on the next page, from the right-hand column, it talks about tape-related long-term complications?

A Yes. It was --

Q And they say there, "Persistent or chronic pain was reported by 13 patients for the retropubic midurethral sling group and 30 patients for transobturator midurethral sling patients"; correct?

A Yes.
Q And so 13 patients --
A Over 3974.
Q -- divided by 3974 is a rate of chronic or persistent pain of .3 percent; correct?
A That's correct.
Q And for 30 patients with the transobturator midurethral slings, divided by 2,432 patients with transobturator midurethral slings, that would yield a persistent or chronic pain rate of 1.2 percent; correct?
A Yes.
Q One of the articles you have in your binder is an article by Jonsson-Funk, et al.?
A Yes.
Q That study looked at 188,454 women who underwent a midurethral sling procedure?
A Yes.
Q And that study showed the nine-year cumulative risk of sling revision or removal was 3.7 percent?
A Yes. Over nine years.
Q And they found that the nine-year risk of sling revision removal for mesh erosion was 2.5 percent; right?
A Yes.
Q You've got a study here by Cecile Unger. Is that a study that you reviewed and relied on in forming your opinions

in this case?
A Yes.
Q And did you also review and rely on the Jonsson-Funk study in forming your opinions in these cases?
A The previous study, yes.
Q In that Unger study, they looked at 3,307 women who underwent sling placement; is that right?
A Yes.
Q And they found that 89 women underwent sling revision?
A Yes. 2.7 percent.
Q And if you do the math there, the rate of sling revision for erosion was 0.57 percent?
A That's right.
Q And the rate of --
A Pain is 0.21 percent.
Q The rate of vaginal pain or dyspareunia causing sling -- or necessitating sling revision?
A Yes.
MR. DEGREEFF: Can I see those, Doctor, the ones you just spoke about?
THE WITNESS: Oh, it was this one here.
MR. DEGREEFF: Is this the only one you were just talking about, or was there another one?
THE WITNESS: No, that was Funk I

think you had there.

MR. DEGREEFF: Tommaselli, what was the other one?

THE WITNESS: Jonsson-Funk.

MR. DEGREEFF: Thank you.

THE WITNESS: This is Welk.

Q (By Mr. Koopmann) You also reviewed a study by Welk and relied on that in forming your opinions in these cases?

A Yes.

Q And this study was a population-based retrospective cohort study that included all adult women undergoing an incident procedure for SUI with synthetic mesh in Ontario, Canada, from April 1st, 2002, through December 31, 2012; is that right?

A Yes.

Q And the number of those women was 59,887?

A Yes.

Q And the author's conclusion was that ten years after SUI mesh surgery, 1 of every 30 women may require a second procedure for mesh removal or revision?

A That's their conclusion, yes.

Q So turn to Page E-3, the primary analysis section. It said, overall 1,307 women, or 2.2 percent underwent mesh removal or revision a median of 0.49 years after receiving a mesh implant for SUI. The sling complication

was treated by the same surgeon responsible for the original procedure in 812 of the 1,307 cases, which was 62.1 percent; is that right?

A Correct. Yes.

Q You also had a study by Nguyen; is that right?

A John Nguyen, yes.

Q Nguyen. And that's a study that you relied on in forming your opinions in these cases?

A Yes.

Q And in this Nguyen study, they looked at all female members of Kaiser Permanente, Southern and Northern California and Hawaii, who underwent sling procedures or pelvic organ prolapse surgeries using implanted grafts of mesh between September 1, 2008, and May 31, 2010; is that right?

A Correct.

Q And they looked at 3,747 sling patients; is that right?

A Yes.

Q And 30 of the 3,747 experienced a vaginal mesh erosion?

A Yes.

Q And that was a 0.8 percent rate for erosions?

A That's correct.

Q One of the articles you had earlier was an article by Schimpf, et al.; is that right? It's right here.

A Okay.

Q And that Schimpf study was a systematic review and meta-analysis of randomized control trials from 1990 through April 2013, with a minimum of 12 months of follow-up?
A Yes.
Q And the RCTs were comparing the sling procedure for SUI to another sling or Burch urethropexy?
A Correct.
Q And they looked at full-length midurethral slings like the TVT and TVT-O?
A Yes.
Q And they looked at single-incision slings like the TVT-Secur?
A Correct.
Q And if you look at Table 1 on Page 71.E5, they list in Table E1 the randomized control trials looking at mini-slings versus any other sling; right?
A Yes.
Q And all of those mini-sling studies that they looked at studied the TVT-Secur except one; is that right?
A Yes.
Q And then in Table 3 of that study, they look at the rates of adverse events by sling type analyzed from randomized control trials, and included adverse event studies; is that right?

A Correct.
Q And they compare, when possible, transobturator slings like the TVT-O, mini-slings like the TVT-Secur, retropubic slings like the TVT retropubic --
A Yes.
Q -- and the Burch procedure and pubovaginal sling procedures; right?
A Yes.
Q And is this table something that you reviewed and relied on in forming your opinions in this litigation?
A I have.
Q And the author's conclusion with respect to the midurethral slings versus the Burch procedure, was that they suggested either intervention based on the cure rates -- the objective cure rates and said the decision should balance on -- balance potential adverse events and concomitant surgeries; right?
A Yes.
MR. DEGREEFF: I don't have anything from Exhibit 4 right here, do I?
MR. KOOPMANN: I don't think so.
Q (By Mr. Koopmann) Another study you have in your binder for the TVT and TVT-O general report is a study by Mohamed Abdel-Fattah; is that right?
A Yes.

Q And that study looked at -- their objective was to determine the lifetime risk of undergoing pelvic floor surgery in a cohort of U.K. parous women, and the reoperation rates for pelvic floor surgery?
A Yes.
Q And they ended up looking at 34,631 women?
A Yes.
Q If you'll turn to Page 5, they talk about some risk factors for reoperation?
A Yes.
Q And they found that the -- that 8.8 percent of the women studied had at least one repeat urinary incontinence surgery?
A Yes.
Q And then they also indicate on the right-hand column that the reoperation rate for urinary incontinence was 3.2 percent in the --
A In the midurethral group.
Q In the midurethral sling group; right?
A Yes.
Q And it was 10.7 percent in the abdominal retropubic surgery group?
A Yes.
Q Is that a Burch procedure?
A That's exactly what that is.

Q In your TVT-Secur general report binder, you have a systematic review and meta-analysis by Colin Walsh; is that right?
A Yes. Yes. 2011?
Q And that study looked at -- well, it was published in 2011; correct?
A Yes.
Q And it looked at 1,178 women who received the TVT-Secur?
A Yes.
Q And that was in ten studies?
A Ten studies.
Q And they found both the objective and subjective cure rate at 12 months was 76 percent?
A Yes.
Q And they found a 2.4 percent incidence of mesh exposure in the first year?
A Yes.
Q And a 1 percent rate of dyspareunia?
A Yes.
Q And a return to theater for complications rate of 0.8 percent?
A Yes.
Q Is this a study that you reviewed and relied upon in forming your opinions about the TVT-Secur sling?
A Yes.

Q Did you also review a study by Mohamed Abdel-Fattah, which was a meta-analysis regarding single-incision mini-slings?
A Yes. But let's find it. Oh, here it is. No. 1. Yes.
Q In that study, they looked at a total of 758 women in nine randomized control trials with a mean follow-up of nine and a half months?
A Yes.
MR. DEGREEFF: Hey, Barry, I'm going to have to object. I mean, all you're doing is sitting here reading documents to him. I mean, if you want to ask him questions about the documents, that's fine, but I feel like you're just reading them to him. I think that's leading.
Q (By Mr. Koopmann) Single-incision midurethral slings were associated with significantly lower patient reported and objective cure rates at 6 to 12 months compared with standard midurethral slings.
Is that what it reports?
A And that was my experience in a study that I contributed, that there was an early -- less pain initially postop, but at the one-year mark was the same as the longer slings.
MR. DEGREEFF: Objection. Form.
Q (By Mr. Koopmann) Then on Page 471, they note that the

single-incision midurethral sling meta-analysis was possible for studies comparing TVT-Secur versus standard midurethral slings; right?

A Yes.

MR. DEGREEFF: Objection to form.

Q (By Mr. Koopmann) And they noted that a trend towards lower rates of patient reported success and objective cure with the TVT-Secur was seen; however, it did not reach statistical significance. Is that right?

A Yes.

MR. DEGREEFF: Objection. Form.

Q (By Mr. Koopmann) And what does that mean, that it did not reach statistic significance?

MR. DEGREEFF: You've got to let me get my objections on the record before you answer, Doctor.

THE WITNESS: Well, what it means is that --

MR. DEGREEFF: Objection. Form.

THE WITNESS: -- there wasn't a statistical difference that was enough to be means tested that it was significant. The P testing was not high enough to -- to say that there's a delta here where Secur was different than the standard midurethral sling.

Q (By Mr. Koopmann) Okay. And then in the right-hand

column under Quality of Life, it indicates that there was a trend towards better quality of life score in the standard midurethral sling group, but it was not statistically significant; is that right?

A Yes.

MR. DEGREEFF: Objection for form. And just to be clear, is my running objection on form still going for leading?

MR. KOOPMANN: I thought it ended because you started objecting again to leading.

MR. DEGREEFF: Well, I actually -- I think what happened is that I forgot that we had a -- we had an agreement that I could -- that it was -- I had a running objection. So if my running objection is still in place, then I'll stop saying objection to form on everything.

MR. KOOPMANN: I'll put it back in place now.

MR. DEGREEFF: Okay. Thanks.

Q (By Mr. Koopmann) So does that basically mean that the quality of life scores between the standard midurethral slings and single-incision midurethral slings was no different?

A They're -- they're close enough that they are the same.

Q And you've reviewed TVT-Secur-related literature,

including randomized control trials, that were both favorable regarding the sling, and unfavorable?

A That's correct.

Q Okay. And you factored all of that in, in forming your opinions about the device?

A Yes.

MR. JONES: Could we see that one, that Abdel-Fattah?

MR. KOOPMANN: Here, I think I've got copies.

MR. DEGREEFF: Do you have copies of all of those that you just did that we could have?

MR. KOOPMANN: Several.

MR. DEGREEFF: Okay.

MR. KOOPMANN: Do you want one to take with you?

MR. DEGREEFF: Yeah.

MR. KOOPMANN: Do you want it now or can I do it after we're done?

MR. DEGREEFF: We can do it after we're done. That's fine.

MR. KOOPMANN: I think those are all the questions I have for you, Dr. Grier. I may have some more if Counsel has some more.

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(Recess from 9:12 p.m. to 9:18 p.m.)

FURTHER EXAMINATION

BY MR. DEGREEFF:

Q Doctor, you mentioned earlier, I believe when Counsel was questioning you, that there was some discord among your colleagues about -- regarding transvaginal mesh.

Do you remember giving that testimony?

A I don't recall. Discord?

Q That's the word you used. Because that's not even a word I would ever come up with.

A There's differing opinions in terms of techniques and how to place it and some people will come up with the idea of putting in drains. It's different iterations of the same surgery that may not follow the IFU. So occasionally someone would come up with a concept like that.

Q Doctor, you're aware that a number of your colleagues believe that transvaginal mesh is not safe?

MR. KOOPMANN: Object to form.

THE WITNESS: I think very few of my colleagues agree to that. If you look at the position papers by the different societies, they're -- they feel that it has efficacy and safety, and it should still be used.

Q (By Mr. DeGreeff) I guess my question was a little

STATE OF WASHINGTON)
) ss
County of Pierce)

I, Cindy M. Koch, CCR, RPR, CRR, CLR, a certified court reporter in the State of Washington, do hereby certify:

That the foregoing deposition of DOUGLAS GRIER, M.D. was taken before me and completed on March 22, 2016, and thereafter was transcribed under my direction; that the deposition is a full, true and complete transcript of the testimony of said witness, including all questions, answers, objections, motions and exceptions;

That the witness, before examination, was by me duly sworn to testify the truth, the whole truth, and nothing but the truth, and that the witness reserved the right of signature;

That I am not a relative, employee, attorney or counsel of any party to this action or relative or employee of any such attorney or counsel and that I am not financially interested in the said action or the outcome thereof;

That I am herewith securely sealing the said deposition and promptly delivering the same to Attorney David DeGreeff.

IN WITNESS WHEREOF, I have hereunto set my signature on the 25th day of March, 2016.

Cindy M. Koch, CCR, RPR, CRR, CLR
Certified Court Reporter No. 2357